UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

BENJAMIN DRESNER, individually and on behalf of all others similarly situated,

Plaintiff,

v.

SILVERBACK THERAPEUTICS, INC., LAURA K. SHAWVER, JONATHAN PIAZZA, RUSS HAWKINSON, PETER THOMPSON, VICKIE L. CAPPS, ROBERT HERSHBERG, SAQIB ISLAM, ANDREW POWELL, JONATHAN ROOT, THILO SCHROEDER, and SCOTT PLATSHON,,

Defendants.

CASE NO. C21-1499 MJP

ORDER ON MOTION TO DISMISS

This matter comes before the Court on Defendants' Motion to Dismiss (Dkt. No. 34). The Court, having reviewed the Motion, Plaintiffs' Opposition (Dkt. No. 37), the Reply (Dkt. No. 38), and all supporting materials and documents, GRANTS the Motion.

BACKGROUND

Plaintiffs bring this case as a potential class action alleging negligence and securities fraud based on the premise that Silverback, and the individually named Defendants, knew or should have known that their developmental drug was not safe or effective as an anti-tumor drug. Therefore, the filings with the Securities and Exchange Commission ("SEC"), press releases and other reports made by Defendants were false and misled investors.

Silverback Therapeutics is a biopharmaceutical company that seeks to develop treatments for cancer, chronic viral infections, and other serious diseases that express a protein called HER2. (First. Am. Compl. ("FAC") ¶ 37 (Dkt. No. 29): Mot. to Dismiss ("Motion") at 3 (Dkt. No. 34).) Silverback developed its lead drug candidate, SBT6050, as a novel treatment for these diseases. (Motion at 3.) SBT6050 is an Antibody-Drug Conjugate that targets tumors, such as breast, gastric, and non-small cell lung cancers. (FAC ¶ 38.) The drug is designed to activate myeloid cells, a class of immune cells that can make up to 10% of the cells in a tumor, and in doing so, promote direct tumor killing and recruitment of other immune cells that can also have tumor killing properties. (Motion at 4.)

In order for SBT6050 to be sold commercially, it must first undergo a clinical trial involving three phases of human testing. Phase 1 trials are designed to determine the pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and "if possible, to gain early evidence on effectiveness." 21 C.F.R. § 312.21. This case arises out of Silverback's disclosures surrounding the Phase 1 testing of SBT6050.

A. SBT6050 Phase 1 Clinical Trial and Silverback's Initial Public Offering

In July 2020, Silverback began a Phase 1 clinical trial that would "monitor key [pharmacodynamic ("PD")] biomarkers in both the blood and the tumor which have been

associated with tumor regression in [the] preclinical mouse studies and was observed in [the] preclinical NHP [non-human primate] studies." (FAC ¶ 42.) The trial would evaluate biomarkers of immune cell activation and anti-tumor activity of SBT6050 in patients that have failed all other available therapies, as well as test the safety and tolerability of SBT6050. (Id.; Declaration of Koji Fukumura, Exhibit A at 3 (Dkt. No. 34-30).) Phase 1 of the trial was broken up into four different parts. Part 1 involved SBT6050 monotherapy dose-escalation and expansion. (FAC ¶ 1.) Part 2 focused on monotherapy dose expansion in tumor-specific cohorts. (Id.) Part 3 tested pembrolizumab (a type of cancer drug) combination dose-escalation. (Id.) And Part 4 looked at a pembrolizumab combination dose expansion cohort. (Id.) In Part 1 of Phase 1, which began in July 2020, Silverback enrolled six patients and administered SBT6050 every two weeks at 0.3 mg/kg each dose. (Fukumura Decl. Ex. A at 130.)

Five months into Part 1 of the Phase 1 trial, on December 3, 2020, Silverback issued common stock that began trading publicly at $21.00 per share. (FAC ¶¶ 4- 5.) At the same time Silverback filed a registration statement and a prospectus with the SEC. (FAC ¶¶ 3-4.) Plaintiffs refer to these documents as the "Offering Documents." (FAC ¶ 4.) Plaintiffs allege the Offering Documents were negligently prepared, contained untrue statements of material fact or omitted facts necessary to make the statements not misleading, and were not prepared in accordance with the rules and regulations governing their preparation. (FAC ¶ 5.)

The December 2020 Offering Documents stated, among other things, that thus far in the trial, Silverback observed changes in pharmacodynamic markers in the first dose cohort and anticipated providing an update on the interim data from the Phase 1 dose-escalation cohorts in the second half of 2021. (FAC ¶ 47.) The Offering Documents also discussed the adverse events (side effects) seen thus far in the clinical patients, as well as risk factors investors should be

aware of, and Silverback's beliefs and goals for SBT6050's marketability. (FAC ¶¶ 47-52; Fukumura Decl. Exs. A, B, C, and D.) The First Amended Complaint highlights certain portions of the Offering Documents' statements of marketability, in particular Silverback's statements that the drug had been designed differently from other anti-tumor drugs, meaning that it could be used in combination with other drugs that are otherwise not typically available for combination treatment. (FAC ¶¶ 50-51.) Silverback believed that, ideally, this would allow the drug to be used in early-line standard of care regiments. (Id.)

B. Silverback's Statements from March 2021 – August 2021

Silverback issued and filed with the SEC its first annual report to investors on March 29, 2021. (FAC ¶ 55.) Much of the report contained information previously disclosed in the Offering Documents. (FAC ¶¶ 55-58.) For instance, the March filing contained the same paragraphs explaining how SBT6050 differed from other anti-tumor drugs, that Silverback anticipated providing an update on the interim data from Phase 1 single agent dose-escalation cohorts in the second half of 2021, and that Silverback had observed changes in patients' pharmacodynamic markers in the first dost cohort. (FAC ¶¶ 55-60) The filing also stated that investors could expect an update from Phase 1, SBT6050 plus pembrolizumab combination, in the first half of 2022, and that enrolled treatment had been initiated in Part 3 of the Phase 1 study. (Fukumura Decl. Ex. E at 24.)

At the same time, Silverback issued a press release, which stated in the pertinent part:

> 2020 was an extraordinary year for Silverback, with the initiation of our first clinical study for SBT6050, in which pharmacological activity was observed in the first dose cohort, the advancement of each of our preclinical programs, expansion of our strong team, and the successful closing of our IPO in December. . .

(FAC ¶ 62.)

The press release further stated that "[c]hanges in pharmacodynamic markers consistent with potential mechanism of action have been observed in patients treated in the first monotherapy dose cohort." (Id.)

Silverback again reported to investors in May and August of 2021, when it filed its first and second quarterly reports for 2021 with the SEC. (FAC ¶¶ 64, 67.) Silverback's May report stated that SBT6050 "continues to advance through monotherapy and pembrolizumab combination dose escalation arms of the Phase 1/1b clinical study" and that it was "on track to deliver interim clinical data from the monotherapy dose escalation arm of the study in the second half of 2021." (FAC ¶ 65.) In August, Silverback issued a press release along with its quarterly filing. (FAC ¶ 67.) The press release stated that Silverback had "observed pharmacodynamic markers in the first monotherapy dose cohort" and that the trial was progressing with "continued robust enrollment." (Id.)

Each time Silverback issued a report or statement, it disclosed that the statements contain "certain forward-looking statements that involved risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements." (See Fukumura Decl. Exs. G, H, I, and J.)

C. Silverback's Statements from September 2021 – March 2022

In September 2021, Silverback issued a press release unrelated to any SEC filing. The press release directed investors to an abstract that disclosed the interim results of its monotherapy and combination therapy dose-escalation studies. (FAC ¶ 69.) The abstract explained that "[a]s of 4 April 2021, 18 patients across 10 tumor types were treated at 4 dose levels." (FAC ¶ 70.) The most frequent adverse effects were chills, diarrhea, fatigue, hypotension, injection site reactions, nausea, pyrexia, and vomiting. (Id.) Dose levels greater than 0.6 mg/kg were evaluated

and dose limiting toxicities were resolved with supportive care. (Id.) Based on this data, Silverback concluded that SBT6050 alone or in combination with pembrolizumab had a manageable safety profile. (Id.) However, among these evaluable patients, only one demonstrated a partial response and three others demonstrated stable disease. (Id.) In response to this news, Silverback's stock price dropped approximately 23% from $19.44 per share to $14.90 per share. (FAC ¶ 71.)

Three days later, Silverback gave an investor presentation that discussed in further detail the data Silverback had collected as of August 1, 2021. (Fukumura Decl. Ex. L. at 9.) Again, Silverback reiterated that SBT6050 had a manageable safety profile and that the common adverse effects were consistent with immune activation. (Id.) Silverback stated that the trial demonstrated "[e]arly signals of anti-tumor activity in a heavily pre-treated heterogenous population." (Id.) Silverback further explained that among 18 evaluable patients, one patient had a partial response, and seven others demonstrated a stable disease. (Id.)

In November 2021, Silverback filed its third quarter report with the SEC. (FAC ¶ 72.) Silverback reiterated findings from its September report, including that the data collected as of August 1, 2021, indicated "proof-of-mechanism through SBT6050's ability to activate myeloid, T and NK cells," as well as "early signs of anti-tumor activity, and no dose limiting toxicities." (Id.) Silverback went on to report that higher SBT6050 dose levels in combination with pembrolizumab showed dose limiting toxicities in three patients, two of whom were able to continue the study at a lower dose, but the third ultimately passed away. (Id.)

On March 31, 2022, Silverback filed its fourth quarter results for the 2021 fiscal year with the SEC. (FAC ¶ 75.) Silverback announced that "the most recent data showed limited monotherapy anti-tumor activity and cytokine-related adverse events that limited the dose in

combination with pembrolizumab." (Motion at 9.) Basically, SBT6050 did not have sufficient anti-tumor activity when used alone, and an effective dosage for anti-tumor activity in combination therapy could not be used due to the severity of the adverse effects. (Id.) As such, Silverback was discontinuing the development of SBT6050, as well as another development drug, SBT6290, because it has a similar clinical profile as SBT6050. (FAC ¶ 75.) As a result of this news, Silverback's stock declined 8.55% to $3.20 per share. (FAC ¶ 76.)

The Plaintiffs in this action filed their original complaint on November 5, 2021. Plaintiffs formulated their claims as actions under Sections 11 and 15 of the Securities Act of 1933 ("Securities Act"); Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"); and SEC Rule 10b-5. Plaintiffs' Securities Act claims pertain only to the Offering Documents, which Plaintiffs allege were prepared negligently. Plaintiffs' Exchange Act claims encompasses all filings, press releases, and statements made during the entire class period from December 3, 2020, to March 31, 2022. With regard to this claim, Plaintiffs allege that Defendants "engaged in a plan, scheme, conspiracy and course of conduct. . . which operated as a fraud and deceit upon Plaintiffs." (FAC ¶ 104.) Similar to their Section 11 claim, Plaintiffs premise this argument on the basis that Defendants knew the trial findings were indicative of the drug's eventual failure, yet they continued to highlight only the positive findings giving the false impression that the trial was going to be successful. Plaintiffs claim that once the drug's limited success became known, the stock dropped and Plaintiffs experienced financial losses.

ANALYSIS

A. Incorporation by Reference and Judicial Notice

Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6). Lee v. City of Los Angeles, 250 F.3d 668,

688 (9th Cir. 2001). However, "[t]here are two exceptions to this rule: the incorporation-by-reference doctrine, and judicial notice under Federal Rule of Evidence 201." Khoja v. Orexigen Therapeutics, Inc., 899 F.3d 998 (9th Cir. 2018); see also Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007) (noting documents incorporated by reference and "matters of which a court may take judicial notice" are properly considered when ruling on a motion to dismiss).

"Incorporation-by-reference is a judicially created doctrine that treats certain documents as though they are part of the complaint itself." Khoja, 899 F.3d at 1002. A defendant may seek to incorporate a document into the complaint "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim. U.S. v. Ritchie, 342 F.3d 903, 908 (9th Cir. 2003). "The doctrine prevents plaintiffs from selecting only portions of documents that support their claims, while omitting portions of those very documents that weaken – or doom – their claims." Khoja, 899 F.3d at 1002.

Here, Defendants and Plaintiffs have each requested that the Court incorporate by reference a number of documents, mostly SEC filings and press releases, which form the basis of Plaintiffs' complaint. Plaintiffs' request that Exhibits A-C be incorporated by reference are documents that are also included in Defendants' request as well. Defendants' Exhibits A-P are incorporated by reference in the Complaint. Neither party opposes consideration of the documents, and these documents form the basis of Plaintiffs' claims. The Court GRANTS Plaintiffs request to incorporate by reference Exhibits A-C, and Defendants' request to incorporate by reference Exhibits A-P.

A court may take judicial notice of facts that are "not subject to reasonable dispute," Fed. R. Evid. 201(b), as well as documents that are referred to in the complaint, that are central to the

plaintiff's claims, and whose authenticity is not disputed. See, e.g., Branch v. Tunnell, 14 F.3d 449, 454 (9th Cir. 1994) overruled on other grounds by Galbraith v. Cty of Santa Clara, 307 F.3d 1119, 1127 (9th Cir. 2002). A court may also take judicial notice of public documents filed with the SEC, Metzler Inv. GMBH v. Corinthian Colleges, Inc., 540 F.3d 1049, 1065 n. 7 (9th Cir. 2008), undisputed matters of public records, Lee, 250 F.3d at 689, records and reports of administrative bodies, Mack v. South Bay Beer Distributors, 798 F.2d 1279, 1282 (9th Cir. 1986), overruled on other grounds by Astoria Fed. Sav. And Loan Ass'n v. Solimino, 501 U.S. 104, 110-11 (1991), and accounting standards, In re Asyst Tech, Inc. Derivative Litig., No. C-06-04669 EDL, 2008 WL 2169021, at *1 n. 1 (N.D. Cal. May 23, 2008).

Plaintiffs and Defendants request the Court take judicial notice of several analyst reports (Plaintiffs' Exhibits D and E, and Defendants' Exhibits R-T). Courts have regularly taken judicial notice of analyst reports, not for the truth of the matter asserted, but "for the purpose of showing that particular information was available to the stock market." Helitrope Gen., Inc. v. Ford Motor Co., 189 F.3d 971, 981 n.18 (9th Cir. 1999); see also, In re Apple Inc. Sec. Litig., No. 19-cv-02033-YGR, 2020 WL 2857397, at *6 (N.D. Cal. June 2, 2020) (noting that courts routinely take judicial notice of analyst reports and providing list of cases). Neither Party objects to or disputes the authenticity or accuracy of the reports. The Court GRANTS Plaintiffs' request to take judicial notice of Exhibits D and E, and Defendants' Exhibits R-T.

Finally, Defendants request the Court take judicial notice of Exhibits Q and U. Exhibit Q is the description of Silverback's clinical trial for SBT6050 that is available at ClinicalTrials.gov, a resource provided by the U.S. National Library of Medicine. The information contained in Exhibit Q is not in dispute, therefore the Court GRANTS Defendants' request to take judicial notice of Exhibit Q. Exhibit U is the U.S. Food and Drug Administration's information page on

clinical research, which discusses the different phases of clinical trials. While Exhibit U is not disputed by Plaintiffs, Defendants appear to want to use this information to counter Plaintiffs' claim that SBT6050 Phase 1/1b trial was designed to and did evaluate efficacy, which is in dispute. The Court cannot take judicial notice of this without potentially making a finding on a disputed fact. As such, the Court DENIES Defendants' request to take judicial notice of Exhibit U.

B. Motion to Dismiss

1. Legal Standard

Under Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss an action for failure to state a claim upon which relief may be granted. In order to survive such a motion, a plaintiff must allege "enough facts to state a claim for relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In determining whether to dismiss a complaint under Fed. R. Civ. P. 12(b)(6), the Court must accept all well-pleaded allegations as true, South Ferry LP, No. 2. v. Killinger, 542 F.3d 776, 782 (9th Cir. 2008), and draw all reasonable inferences in favor of the plaintiff, Twombly, 550 U.S. at 555. In other words, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal quotation omitted). However, these tenets are "inapplicable to legal conclusions." Id. A pleading that only offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555. If the plaintiff "ha[s] not nudged [its] claims across the line from conceivable to plausible, [the] complaint must be dismissed." Id. at 570. "Dismissal without leave to amend is improper unless it is clear, upon de novo review, that

the complaint could not be saved by any amendment." Gompper v. VISX, Inc., 298 F.3d 893, 898 (9th Cir. 2002) (internal quotation and citation omitted).

2. Section 11 Claim

Defendants move to dismiss Plaintiffs' Section 11 claim on the theory that it is subject to the heightened pleading standard of Federal Rule of Civil Procedure 9(b), but that even if Federal Rule of Civil Procedure Rule 8(a) applies, Plaintiffs still cannot meet that standard. The Court agrees with Defendants. Plaintiffs' Section 11 claim is comprised of paragraphs taken from the Offering Documents and a concluding paragraph stating the claims are false and misleading. Plaintiffs do not attempt to explain what in the paragraphs from the Offering Documents are false and misleading, let alone why they are material. Plaintiffs' failure to do so means that the claim does not clear even Rule 8(a) pleading standards.

a. Elements of Claim

Section 11 of the Securities Act creates a private remedy for any purchaser of a security if the registration statement published in connection with the offering "contain[s] an untrue statement of a material fact or omit[s] to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). To prevail on a Section 11 claim, a plaintiff must prove "(1) that the registration statement contained an omission or misrepresentation, and (2) that the omission or misrepresentation was material, that is, it would have misled a reasonable investor about the nature of his or her investment." In re Daou Sys., Inc., 411 F.3d 1006, 1027 (9th Cir. 2005) (internal quotation and citation omitted). Under Section 11, "[l]iability against the issuer of a security is virtually absolute, even for innocent misstatements," if the plaintiff can show a material misstatement or omission. Herman & MacLean v. Huddleston, 459 U.S. 375, 382 (1983).

b. Applicable Pleading Standard

Typically, Federal Rule of Civil Procedure 8(a) applies to a Section 11 claim because they do not require an allegation of scienter. Daou, 411 F.3d at 1027. But if the Section 11 claim sounds in fraud, the complaint must satisfy the particularity requirements of Federal Rule of Civil Procedure Rule 9(b). Rubke v. Capital Bankcorp LTD, 551 F.3d 1156, 1161 (9th Cir. 2009).

"To ascertain whether a complaint sounds in fraud, we must normally determine, after a close examination of the language and structure of the complaint, whether the complaint alleges a unified course of fraudulent conduct and relies entirely on that course of conduct as the basis of a claim." In re Rigel Pharms, Inc. Sec. Litig., 697 F.3d 869, 885 (2012) (internal quotation and citation omitted). When a complaint employs the exact same factual allegations to allege violations of Section 11 as it uses to allege fraudulent conduct under Section 10(b) of the Exchange Act, we can assume that it sounds in fraud. See Daou, 411 F.3d at 1028. A plaintiff cannot escape the requirements of Fed. R. Civ. P. 9(b) with a general disclaimer that a claim is based on negligence rather than fraud. Wagner v. First Horizon Pharm. Corp., 464 F.3d 1273, 1278 (11th Cir. 2006); In re Stratosphere Sec. Litig., 1 F.Supp.2d 1096, 1104 (D. Nev. 1998).

Rule 9 applies to Plaintiffs' Section 11 claim. Though Plaintiffs explicitly disclaim any allegation of fraud, recklessness or intentional misconduct, the facts alleged by Plaintiffs indicate that they rely on the same allegations to support their Section 11 claim as the Section 10(b) fraud claim.

There are two main problems with Plaintiffs' arguments. First, the Offering Documents that Plaintiffs base their Section 11 negligence claim on are also part of their Section 10(b) fraud claim. The class period for the 10(b) claim begins on December 3, 2020, the same day the Offering Documents became effective, and Silverback's common stock began trading. (FAC ¶¶

1, 3, 4.) Plaintiffs' claim that during the class period, Defendants engaged in a course of conduct which operated as fraud. (FAC ¶ 104.) The same Offering Documents Plaintiffs claim are based in negligence also serve as the starting period for the fraudulent course of conduct under Plaintiffs' Section 10(b) claim. And Plaintiffs did not refute this during oral argument. Rather, Plaintiffs specified that the Offering Documents underpin both the Section 11 claim and the Section 10(b) claim. As such, Plaintiffs allege a unified course of conduct and provide no basis for why their Section 11 claim is grounded in negligence.

Second, many of the statements Plaintiffs allege are false and misleading in the Offering Documents are repeated verbatim in Silverback's later SEC quarterly filings. Plaintiffs identify these statements as false and misleading, but claim they were made through a fraudulent course of conduct in order to support their Section 10(b) claim. (Compare FAC ¶¶ 50,56; 51, 57; and 52, 58.) Essentially, Plaintiffs are alleging the same set of facts are fraudulent in one claim, but negligent in another. And Plaintiffs do not attempt to provide a rationale for why the statements iterated in the Offering Documents are negligent, but fraudulent when made later or as part of their Section 10(b) claim.

Because Plaintiffs fail to provide an adequate rationale for why their Section 11 claim is based on negligence, and the same documents are part of their Section 10(b) fraud claim, the Court finds Fed. R. Civ. P. 9(b) applies to Plaintiffs' Section 11 claim.

c. Plaintiffs' Section 11 Claim Fails to Satisfy Rule 9(b)

In order to satisfy Rule 9(b)'s pleading requirements, Plaintiffs must "state with particularity the circumstances constituting fraud. . ." Fed. R. Civ. P. 9(b). In other words, the complaint must "set forth what is false or misleading about a statement, and why it is false." Yourish v. Cal. Amplifier, 191 F.3d 983, 993 (9th Cir. 1999).

Plaintiffs have failed to satisfy these requirements. As an initial matter, Plaintiffs' Complaint is "puzzle pled," which makes it difficult to determine what specifically they allege is misleading. In oral arguments, Plaintiffs clarified that there are four categories of misstatements that they allege were present in the Offering Documents and during the class period.

The first category and what appears to be the crux of Plaintiffs' claim is Silverback's statements that it "observed changes in pharmacodynamic markers in the first dose cohort," associated with tumor regression. (FAC ¶¶ 47, 49, 50.) Plaintiffs claim that this is misleading because Silverback did not disclose that despite seeing these changes, it observed limited anti-tumor activity. But Plaintiffs fail to demonstrate why this statement is false or misleading. Rather, Plaintiffs appear to equate Silverback's statements that it "observed changes in pharmacodynamic markers" to Silverback claiming SBT6050's efficacy. Plaintiffs do not explain how Silverback's statements are the same as stating efficacy, and critically, Plaintiffs fail to contextualize the statement.

For example, Paragraph 49 of the First Amended Complaint contains a large block quote from the Offering Documents. Within this, it states that "[c]hanges in pharmacodynamic markers consistent with the potential mechanism of action have been observed in treated patients where data are available." (FAC ¶ 49.) The paragraph continues to state explicitly what these changes were: "This includes increases in plasma levels of CRP (C-reactive protein), a marker of inflammation, increases in MCP-1, IP-10 and IL-6, which are indicative of myeloid cell activation, increases in IFNg, which is a marker for T and NK cell activation, and decreases in hemoglobin which we believe to be due to macrophage phagocytosis." (Id.) As such, not only does Silverback state that the changes are consistent with potential mechanism of action, but it also explains exactly what changes were observed. Nowhere in this statement did Silverback

represent that this means the drug is efffective. And Plaintiffs do nothing to explain why the statements are false in the Complaint. In their Opposition to the Motion to Dismiss, Plaintiffs retreat from their Complaint's allegations, arguing that "[w]hether Defendants had indeed observed changes in pharmacodynamic markers. . . is beside the point." (Opposition at 12 ("Opp") (Dkt. No. 37).) This appears to be a concession that the statement is not false, and Plaintiffs have failed to demonstrate its falsity.

Plaintiffs also fail to demonstrate that the statement was misleading. After Plaintiffs walk back their claim that the statement is false, they pivot to argue that the statement contains an omission, thereby giving investors the false impression that they observed "promising signs of efficacy." (Opp. at 13.) In support of this argument, Plaintiffs argue that all of the six patients enrolled in the trial at the time of the IPO later discontinued the study due to disease progression. (Id.) The problem with this argument is that the data supporting this assertion was presented to investors in September 2021, nine months after the initial public offering, and Plaintiffs do not allege that the data was available at the time of the IPO. (See Declaration of Tamar Weinrib, Exhibit A (Dkt. No. 37-1).) In contrast, the Registration Statement, approved by the SEC on December 3, 2020, disclosed that of the six patients initially enrolled, two did not complete the dose-limiting toxicity period and had to be replaced. (Fukumura Decl. Ex. C at 129.) The statement further reported that as of November 25, 2020, only two patients from the first cohort had formal reassessments of their tumor status. (Id.) One showed stable disease, the other showed a reduction in the tumor size. (Id.) So at the time the statement was made in December 2020, there is no indication that it was misleading, and Plaintiffs fail to demonstrate otherwise.

The second category of misstatements Plaintiffs identified in their oral argument is Silverback's statements regarding the development of a second drug SBT6290, that was

designed to work using the same mechanism as SBT6050. But a review of the Amended Complaint demonstrates that Plaintiffs only identify statements regarding SBT6050 for their arguments as to misstatements made in the Offering Documents. (See FAC ¶¶ 47-53.) Plaintiffs' failure to identify any statements regarding SBT6290 made in the Offering Documents dooms any arguments that they have met the pleading standards under Rule 9(b).

Plaintiffs' third identified category has to do with safety. In the Amended Complaint, Plaintiffs identify a large block quote from the Offering Documents that discusses adverse events and concludes that at the time of the IPO, no dose limiting toxicities had been observed and the most common adverse events were flu-like symptoms and redness and swelling at the injection site. (FAC ¶ 49.) Critically, Plaintiffs' concluding paragraph that references all of the statements identified from the Offering Documents fails to mention any false or misleading statements that have to do with safety, which means Plaintiffs fail to even allege that the Offering Documents contain false or misleading statements regarding the safety of SBT6050. As such, they cannot meet Rule 9(b) standards for this category of statements.

Finally, Plaintiffs' fourth category refers to Silverback's statements regarding SBT6050's addressable market. Again, Plaintiffs extract a large block quote from the Offering Documents that discusses current treatments on the market and their contrast to SBT6050. (See FAC ¶ 52.) Following this, Plaintiffs have the concluding paragraph that states "(i) SBT6050 showed limited anti-tumor activity in patients treated with only SBT6050 in Phase 1/1b; (ii) accordingly, the Company had overstated SBT6050's commercial and/or clinical prospects. . ." (FAC ¶ 53.) These conclusory allegations hardly suffice to state what specifically is false or misleading about the preceding paragraph and why. Therefore, Plaintiffs' fail to meet Rule 9(b) standards for this category of statements as well.

Plaintiffs' allegations regarding the Offering Documents contains a patchwork of block quotes taken from the Offering Documents with a conclusory paragraph that declares all the previous paragraphs false or misleading. Plaintiffs make no attempt to explain what is false or misleading about these statements and why they are false. As such, Plaintiffs have failed to meet their burden under Rule 9(b). The Court DISMISSES without prejudice Plainitffs' Section 11 claim for failure to meet the pleading requirements under Fed. R. Civ. P. 9(b).

d. Plaintiffs' Section 11 Claim Fails to Satisfy Rule 8(a)

It bears mentioning that regardless of whether Rule 9(b) applies, Plaintiffs' Section 11 claims still fails under Rule 8(a).

Defendants argue that Plaintiffs engage in improper "puzzle pleading." The Court agrees. "Puzzle pleading" places "the burden on the reader to sort out the statements and match them with the corresponding adverse facts to solve the 'puzzle' of interpreting Plaintiffs' claims." Wenger v. Lumisys, Inc., 2 F.Supp.2d 1231, 1244 (N.D.Cal. 1988). Even under Rule 8(a), Plaintiffs must set forth a short and plain statement containing plausible allegations that: (1) the registration statement contained an omission or misrepresentation, and (2) the omission or misrepresentation was material. Daou, 411 F.3d 1027. Courts in this Circuit have held that "puzzle pleadings" fail to satisfy Rule 8 because they fail to set forth a short and plain statement. In re Splash Tech. Holdings, Inc. Sec. Litig., 160 F.Supp.2d 1059, 1075 (N.D.Cal. 2001); Wenger, 2 F.Supp.2d at 1244.

Here, Plaintiffs identify six paragraphs from the Offering Documents that are purportedly false or misleading. (See FAC ¶¶ 47-52.) All but one of these paragraphs consist of large block quotes. (Id.) The block quotes contain technical language about the SBT6050 and the trial. The one paragraph that is not a block quote simply states:

> Moreover, Defendants touted the advantage of SBT6050 over untargeted TLR8 small molecule therapeutic candidates from other companies which "have resulted in an adverse event profile that we believe has limited achieving a dose level sufficient to produce the desired therapeutic benefit."

(FAC ¶ 48.)

Following the block quotes is a generalized list of reasons of why the Offering Documents made "false and/or misleading statements and/or failed to disclose." (FAC ¶ 53.) So not only does the Complaint fail to explain what from the block quotes is misleading and why it was material, but it also fails to explain whether the statements contain an omission or are misleading for other reasons.

In opposing the Motion to Dismiss, Plaintiffs do little to clarify what language from the block quotes contains misrepresentations or omissions. (See Opp.) Plaintiffs try to paper over this by claiming that their "[c]omplaint is carefully organized, alleges each misleading statement and related omission, including date and the author thereof, and after each group of misstatements, lists the reasons why those statements were misleading." (Opp. at 20.) This bold proposition does not come close to describing the actual Complaint. The lists of reasons as to why the statements in the Offering Documents are misleading are generalized and for the Section 10(b) claim, the reasons are copied and pasted verbatim after each section. Plaintiffs do not provide adequate allegations as to what is misrepresented or omitted from each statement. Even if the Court were to accept all "well pleaded factual allegations as true" Plaintiffs do nothing more than take Silverback's SEC filings and press releases and add a legal conclusion to them, thus creating a claim based only on "labels and conclusions." See Twombly, 550 U.S. at 555.

The Court finds Plaintiffs' failure to meet the pleading standards under Fed. R. Civ. P. 8(a) as an additional reason for dismissing Plaintiffs' Section 11 claim.

3. Section 10(b) and SEC Rule 10b-5 Claim

Section 10(b) and 10b-5 claims are subject to heightened pleading standards under the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Rule 9(b). Defendants argue that Plaintiffs have failed to meet this standard. The Court agrees. Plaintiffs' pleading for the 10(b) claim follows the same format as their Section 11 claim, and therefore contains all of the same issues. The difference is here, Plaintiffs cannot skirt the higher pleading requirements. Because Plaintiffs fail to allege the particularities of why Defendants' statements are false and misleading, as well as allegations of scienter, they fail to satisfy the heightened pleading standards.

a. Elements of Claim

Section 10(b) provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security. . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe. . ." 15 U.S.C. § 78j(b). SEC Rule 10b-5 makes it unlawful for any person to use interstate commerce:

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To prevail on a Section 10(b) claim, a plaintiff must prove "(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." Daou, 411 F.3d at 1014. At

the pleading stage, a complaint stating claims under Section 10(b) and Rule 10b-5 must satisfy the dual pleading requirements of Rule 9(b) and the PSLRA. Id.

b. Falsity

Defendants primarily argue that Plaintiffs failed to plead a material misrepresentation or omission of fact. The Court agrees.

Under the PSLRA, "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). "By requiring specificity, the PSLRA prevents a plaintiff from skirting dismissal by filing a complaint laden with vague allegations of deception unaccompanied by a particularized explanation stating why the defendant's alleged statements or omission are deceitful." In re Nektar Therapeutics Sec. Litig., 34 F.4th 828, 835 (9th Cir. 2022) (internal quotation and citation omitted).

The Ninth Circuit has affirmed dismissals due to lack of falsity where plaintiff's allegations are based on general statements. See Metzler Inv. GMBH v. Corinthian Colleges, Inc., 540 F.3d 1049, 1070 (9th Cir. 2008) (noting that the Ninth Circuit "has consistently held that the PSLRA's falsity requirement is not satisfied by conclusory allegations. . . based on the plaintiff's allegations of fraud generally."); Ronconi v. Larkin, 253 F.3d 423, 429-32 (9th Cir. 2001). In Ronconi, the Ninth Circuit affirmed the dismissal of a securities action where plaintiffs challenged the defendants' statements to analysts that the company's sales growth was accelerating. The complaint alleged that this was false when made because the sales growth was not accelerating. The Ninth Circuit found that the statement was material and the complaint properly stated why it was false. Id. at 430-31. But the Ninth Circuit still affirmed the dismissal because plaintiffs simply asserted that statement was false at the time it was made without

putting forth specific facts or evidence that demonstrated the falsity of the statement and that defendants were aware or should have been aware that it was false. Id. As such, plaintiffs' conclusory allegations were insufficient to meet the PSLRA's pleading requirements. Id. at 431.

As in Ronconi, Plaintiffs have failed to demonstrate falsity. Plaintiffs utilize block quotes taken from Silverback's quarterly filings and press releases without stating what part of the statements are false, why they are false and any allegations of scienter. After each section of block quotes related to a filing, Plaintiffs repeat verbatim the same vague conclusory allegation that:

> The foregoing statements were false and misleading because (i) SBT6050 showed limited anti-tumor activity in patients treated with only SBT6050 in Phase 1/1b; (ii) an overwhelming percentage of trial participants withdrew from the trial due to disease progression; (iii) SBT6050 did not have a manageable safety profile; and (iv) accordingly, the Company had overstated SBT6050's commercial and/or clinical prospects.

(FAC ¶¶ 63, 66, 68.)

Absent an explanation as to why the statements are false or misleading, Plaintiffs' claimed reasons fail to demonstrate what about the block quotes are false or misleading. This is further demonstrated by the act that several times the block quote contains information that is irrelevant to Plaintiffs' conclusion. For instance, Plaintiffs highlight the two following paragraphs from Silverback's 10-Q filing and associated press release:

> In our first quarter as a public company, our team continues to execute on Silverback's mission to bring tissue targeted therapies to patients in need,' said Laura Shawver, Ph.D., chief executive officer of Silverback. We are on track to report interim clinical data for SBT6050 in the second half of this year, and we are equally excited about the progress and preclinical data emerging from SBT6290 and SBT8230, highlighting the broad applicability of our ImmunoTAC platform.

And

> SBT6050 (HER2-TLR8 Immuno TAC) continues to advance through monotherapy and pembrolizumab combination dose escalation arms of the Phase 1/1b clinical

> study. Silverback is on track to deliver interim clinical data from the monotherapy dose escalation arm of the study in the second half of 2021.

(FAC ¶ 65.)

Nothing in these two paragraphs discusses the efficacy of SBT6050, the continued enrollment of participants, or its safety profile. It does not even appear to fall into one of Plaintiffs' four categories of misstatements. Plaintiffs say nothing about what specifically is false or misleading about these two paragraphs and why. And the information contained in the paragraphs hardly seems material to investors – it simply tells investors when to expect an update. Though the Court acknowledges that some of the block quotes contain more relevant information, at no point do Plaintiffs plead specific facts or put forth documentation articulating why these block quotes are materially misleading or that the statements were false and misleading when made.

Because Plaintiffs fail to specify what statements within the block quotes are misleading, along with the reason the statement is misleading, they fail to meet their burden to plead falsity. The Court GRANTS Defendants' Motion to Dismiss the Section 10(b) claim for failure to plead falsity.

c. Scienter

Plaintiffs also fail to advance sufficient allegations of scienter.

A Section 10(b) fraud complaint must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "The court must determine whether all the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 991 (9th Cir. 2009) (internal citation and quotation omitted). When "determining whether the pleaded facts give rise

to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." Id. Essentially, a complaint survives a motion to dismiss "if the malicious inference is at least as compelling as any opposing innocent inference." Id.

To adequately demonstrate that the "defendant acted with the required state of mind," a complaint must "allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." Daou, 411 F.3d 1014-15 (internal citation omitted). Critically, deliberate recklessness is more than recklessness or motive to commit fraud – it is "an *extreme* departure from the standards of ordinary care," which "presents a danger of misleading buyers or sellers that is either known to the defendant or so *obvious* that the actor must have been aware of it." Zucco Partners, 552 F.3d at 991 (emphasis in the original).

Plaintiffs' claims are premised on their belief that Defendants knew SBT6050 was not effective and did not have a manageable safety profile yet continued to omit that information every time they issued a statement. Plaintiffs base this argument on the fact that the trial was "open label" and therefore Defendants "had access to trial data in real time from day one." (Opp. at 21.) Plaintiffs also put forth a Confidential Witness ("CW") 1 in support of their argument, who states that Defendant Shawver (Silverback's CEO and Director) held company wide meetings every two weeks to report and discuss trial data. (FAC ¶ 44.) Though CW1 states these meetings were companywide, Plaintiffs do not put forth any evidence that all the Defendants attended these meetings, let alone every single one, and whether at any point during these meetings it became apparent that SBT6050 was ineffective and lacked a manageable safety profile.

During oral argument, Plaintiffs claimed that the logical inference from these meetings is that SBT6050's safety and efficacy were discussed. But the Court is unwilling to make this

assumption. Despite having a confidential witness who attended the meetings, Plaintiffs do not allege that CW1 can confirm what data was discussed, that safety and efficacy were discussed, when they were discussed, and what documents and data were presented at these meetings. Plaintiffs do nothing more than state CW1 attended the meetings and the likely inference from these meetings is that safety and efficacy were discussed. This argument is unconvincing.

Plaintiffs rely primarily on In re Amgen Inc Sec. Litig., No. CV072636PSGLAX, 2014 WL 12585809 (C.D. Cal. Aug. 4, 2014) (not reported) in support of their assertion that an open label trial and biweekly meetings support a strong inference of scienter. In Amgen, plaintiffs filed securities fraud claims against the company, along with its officers and directors, alleging that they made a series of misleading statements and omissions concerning the safety of two of Amgen's flagship drugs. Id. at *1. On its face, Amgen and this case sound similar, but the facts are very different. In Amgen, the FDA concluded the company had misstated the results of two completed studies that defendants had previously submitted to the FDA. Id. at *3. Additionally, a trial of the drug conducted by an outside group was discontinued due to poor health outcomes, which defendants failed to inform investors of . Id.at *2. Plaintiffs also had specific statements from meetings that contradicted the findings from these studies and demonstrated that these statements were made after the studies were concluded. Id. at *2-3. The court found that "[w]here a strong inference suggests that a defendant was on notice of clinical findings before making contradictory public statements, the defendant's conduct is at least "deliberately reckless" under Section 10(b)." Id. at *9.

Here, Plaintiffs put forth no evidence suggesting that Defendants were on notice of clinical findings that contradicted their public statements at the time those statements were made other than to point to the trial's "open label." As Defendants rightfully argue, the trial proceeded

in distinct parts involving different patient cohorts and different dosages. (Motion at 5.) Meaning that each part of the trial produced new and different data that was not previously available. (Id.) Plaintiffs' claims that Defendants had to have known SBT6050 was not effective or safe simply because the trial was open label is hardly demonstrative of a strong inference of scienter absent evidence that the information was actually available when Defendants made the statements. Additionally, whereas here, Plaintiffs seek to hold individual defendants and Silverback liable, the Ninth Circuit requires Plaintiffs to allege scienter with respect to each of the defendants. See Oregon Pub. Emps. Ret. Fund v. Apollo Grp. Inc., 774 F.3d 598, 607 (9th Cir. 2014). Plaintiffs do not attempt to allege scienter with respect to each of the Defendants other than to point to the company wide meetings. And it is not clear that the public statements and filings are false, let alone "so dramatically false that they would create a strong inference that at least some corporate officials knew of the falsity upon publication." Id. at 607-08.

A holistic view from the Court similarly does not save Plaintiffs. The only facts Plaintiffs put forth in support of scienter are the biweekly meetings and the trial's open label. Plaintiffs supply no additional facts regarding pertinent information that arose during the meetings or that data became available to Defendants that would contradict later statements. These facts are insufficient to give rise to a strong inference of scienter.

The Court finds Plaintiffs' failure to plead scienter as an additional ground to GRANT the Motion to Dismiss.

4. Section 15 and Section 20(a) Claims

Section 15 and Section 20(a) both require underlying primary violations of the securities laws. 15 U.S.C. §§ 77o, 78t(a); Rigel Pharms, 697 F.3d. Because Plaintiffs have failed to

adequately plead a violation of the federal securities laws, Plaintiffs' Section 15 and Section 20(a) claims are DISMISSED without prejudice.

CONCLUSION

Plaintiffs' First Amended Complaint fails to allege with the requisite particularity that Silverback and the individually named Defendants made materially misleading statements and omissions in the Offering Documents and during the class period in violation of Section 11 of the Securities Act and Section 10(b) of the Exchange Act. The Court therefore GRANTS Defendants' Motion to Dismiss without prejudice.

Should Plaintiffs choose to file an amended complaint, they must do so within thirty (30) days of this Order. Failure to do so will result in a dismissal of Plaintiffs' claims with prejudice.

The clerk is ordered to provide copies of this order to all counsel.

Dated November 4, 2022.

Marsha J. Pechman
United States Senior District Judge